GP 1636

PATENT
ATTORNEY DOCKET NO. 07678/062004

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Elaine Fabrizio
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Zhu et al.	Art Unit:	1636
Serial No.:	09/613,486	Examiner:	K. Katcheves
Filed:	July 11, 2000	Customer No.:	21559
Title:	GRAPEVINE LEAFROLL VIRUS (TYPE 2) PROTEINS AND THEIR USES		

Commissioner for Patents
Washington, D.C. 20231

REPLY TO EXAMINER'S ACTION

In reply to the Examiner's Action mailed in the above-captioned case on March 26, 2002, Applicants submit the following remarks.

REMARKS

Claims 1, 2, and 11-18 are withdrawn from consideration as being directed to non-elected inventions. Claims 3-10 are pending. Claims 3-10 were rejected under the judicially created doctrine of non-obviousness type double patenting and under 35 U.S.C. § 112, first paragraph. Each of these rejections is addressed below.

Sequence Requirement

The specification was objected to for failing to comply with the requirements set forth in 37 C.F.R. § 1.821-1.825. As is noted in the concurrently filed Reply to Notice to Comply with Sequence Requirements (courtesy copy enclosed), Applicants amend the specification to include a Sequence Listing and to refer to all sequences by their sequence identifiers, and submit paper and computer readable copies of the Sequence Listing, which are in compliance with 37 C.F.R. § 1.821-1.825.

Rejections under the Judicially Created Doctrine of Non-Obviousness Type Double Patenting

Claims 3-10 were rejected under the judicially created doctrine of non-obviousness type double patenting as being unpatentable over claim 2 of U.S. Patent Number 6,197,948. A terminal disclaimer will be submitted to address this rejection, after allowable subject matter has been indicated, if appropriate.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 3-10 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that is not adequately described in the specification. The present claims are generally directed to DNA molecules encoding grapevine leafroll virus type 2 proteins and polypeptides as well as to vectors, cells, and plants containing such DNA molecules.

In rejecting the claims, the Office states (page 5, page 6):

> Applicant's claims are broadly drawn to nucleic acids encoding any peptide of grapevine leafroll virus, a polyprotein, an RNA dependent RNA polymerase, a heat shock 70 protein, a heat shock 90 protein, a diverged coat protein, and a coat protein ... The specification does not disclose what features are necessary and required for any one of these nucleic acid molecules to maintain their respective activities. Applicant fails to specifically disclose what sequences these genes embrace nor does the specification disclose mutations, additions, or deletions that can be tolerated to produce these nucleic acid molecules and maintain their characteristics as heat shock protein, coat protein or any grapevine leafroll virus protein. Absent such teachings and guidance as to the structure-function relationship of these sequences, the specification does not describe the claimed genuses in such full, clear, concise, and exact terms so as to indicate that Applicant had possession of the invention at the time of filing the present application.

As an initial matter, Applicants note that the present claims are directed to DNA molecules encoding a grapevine leafroll virus type 2 (GLRaV-2) protein or polypeptide, and not to any grapevine leafroll virus peptide or protein, as is asserted by the Office.

The M.P.E.P. states (§ 2163.02; Eighth Edition, August 2001):

> [A]n objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed."

In applying this standard, the Federal Circuit has held that the specification must convey with reasonable clarity to a skilled artisan that the inventor "was in possession of the invention" at the time of filing. *Vas Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19

U.S.P.Q.2d 1111 (Fed. Cir. 1991).

As is stated in the specification, for example, at page 64, lines 20-22, Applicants cloned and sequenced about 85% of the GLRaV-2 genome. It was not until Applicants sequenced the GLRaV-2 genome that the nine open reading frames described in the specification were, in fact, identified. Applicants not only provide the nucleic acid sequences of these GLRaV-2 open reading frames, but also describe the polypeptides encoded by these sequences. As is noted in the specification, for instance, in Example 6, beginning on page 64, open reading frame 1a (ORF1a) encodes a polypeptide having two papain-like protease domains that have significant similarity to the papain-like leader protease of Beet Yellows Virus; ORF1b encodes a polypeptide with a molecular mass of 52,486 Da containing RdRP domains; ORF2 encodes a polypeptide which has a molecular mass of 6,297 Da and which contains a stretch of non-polar amino acids; ORF3 encodes a polypeptide with a molecular mass of 65,111 Da which, based on homology, is an HSP70 cellular heat shock protein; and ORF6 encodes a polypeptide which is similar to other closterovirus coat proteins and which has a molecular mass of 21,661 Da.

In view of Applicants' detailed description of the proteins and polypeptides encoded by the GLRaV-2 nucleic acid sequences, one skilled in the art would be able to identify DNA molecules encoding such proteins and polypeptides in other GLRaV-2 viruses using nothing more than standard methods. Moreover, the specification describes exemplary methods, e.g., high stringency hybridization, that a skilled artisan may use to

identify the claimed DNA molecules in other GLRaV-2 closteroviruses (see, for example, page 48, lines 6-12, and page 59, line 31, to page 32, line 14). In addition, given the substantial nucleic acid sequence information disclosed in the specification, one skilled in the art would know how to identify the remainder of the GLRaV-2 nucleic acid sequence using standard methods, such as those described at page 60, line 29, to page 61, line 16, and at page 62, line 1, to page 63, line 24. Accordingly, the invention clearly encompasses not only the nucleic acids of the disclosed GLRaV-2 strain, but also those of related GLRaV-2 strains.

Furthermore, Applicants submit that the claimed expression vectors, host cells, and transgenic plants are also adequately described in the specification. Exemplary expression vectors are described at page 48, line 29, to page 49, line 25; exemplary host cells are described at page 49, lines 26-31; and exemplary plants into which a vector of the invention may be introduced are described at page 52, line 9, to page 53, line 32.

In sum, there can be no question that Applicants were in possession of the claimed DNA sequences at the time their application was filed, and that one skilled in the art would recognize Applicants' disclosure as a description of the invention as defined by the present claims. As a result, Applicants' specification clearly satisfies the written description requirement, as set forth in the case law and in the M.P.E.P., and Applicants request reconsideration and withdrawal of the § 112 rejection.

CONCLUSION

Applicants submit that the application is in condition for allowance and such action is respectfully requested.

Applicants note that the Examiner's Action was mailed to the incorrect address. Effective immediately, please address all communication in this application to:

Paul T. Clark
Clark & Elbing LLP
101 Federal Street
Boston, MA 02110

Enclosed is a petition to extend the period for replying for three months, to and including September 26, 2002. If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: September 24, 2002

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COPY

Copy of #10 + #11

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AMENDMENT

In reply to the Notice to Comply with Sequence Requirements included with the Office Action mailed on March 26, 2002, Applicants amend the application as follows:

In the Specification:

Insert the Sequence Listing submitted with the accompanying statement under 37 C.F.R. §§ 1.821-1.825 at the end of the specification.